DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0002]

Memorandum on the Use of an FDA Cleared or Approved Sterile Connecting Device in Blood Bank Practice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a memorandum dated August 5, 1994, to all registered blood establishments. In the August 5, 1994, memorandum, the Center for Biologics Evaluation and Research (CBER) recommends practices and procedures in the use of sterile connecting devices (STCD's). CBER also advises that certain uses of these devices may create a new product or significantly modify a regulated product, such that approval of a license application or an application supplement is required. This memorandum provides information to registered blood establishments on the use of STCD's.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the memorandum to the Congressional and Consumer Affairs Branch (HFM–12), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to INTERNET may request this document from ''Mem8—05—94@A1.cber.fda.gov''. The document may also be obtained by calling CBER FAX Information System at 301–594–1939 from a FAX machine with a touch tone phone attached or built in. Submit written comments on the memorandum to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The memorandum and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Betty J. Poindexter, Center for Biologics Evaluation and Research (HFM–335), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–496–2577.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a memorandum to all registered blood establishments on the use of an FDA cleared or approved STCD. STCD's produce sterile welds between two pieces of compatible tubing. This procedure permits sterile connection of a variety of containers and/or needles. This document describes recommended practices and procedures for the use of these devices.

The memorandum provides guidance on the common uses of STCD's as follows: (1) Adding a new or smaller needle to a blood collection set; (2) preparing components; (3) pooling blood products; (4) preparing an aliquot for pediatric use and divided units; (5) connecting additional saline or anticoagulant lines during an automated plasmapheresis procedure; (6) attaching processing solutions; (7) adding an FDA-cleared leukocyte reduction filter; and (8) removing samples from blood product containers for testing.

The memorandum also presents general guidance as well as specific information and examples concerning specifications for submission of applications and application supplements to FDA addressing the use of a STCD. It also includes an appendix with the currently approved dating periods for blood components and source plasma (21 CFR 610.53) and currently recommended dating periods for automated plateletpheresis products (see Revised Guideline for Collection of Platelets, Pheresis (54 FR 3852, January 26, 1989)).

As with other memoranda, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The memorandum is intended to provide information and does not set forth new requirements. The procedures cited in the memorandum are recommendations. FDA anticipates that blood establishments may develop alternative procedures and discuss them with FDA. FDA may find those alternative procedures acceptable. FDA recognizes that advances may continue in the use of STCD's and that this document may become outdated as those advances occur. The memorandum does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any private person, but is intended merely for guidance.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the memorandum. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revisions to the memorandum are warranted.

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–5061 Filed 2–28–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0051]

Solvay Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 11 Abbreviated Antibiotic Applications and 11 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 11 abbreviated antibiotic applications (AADA's) and 11 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: March 31, 1995.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

AADA No.	Drug	Applicant
60–128	Ampicillin Trihydrate	IBI, Giovanni Lorenzini S.p.A., 20139 Milano, Italy.
60–130	Ampicillin	Do.
61–659	Erythromycin Delayed-Release Tablets, U.S.P., 250 milligrams (mg)	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
61–818	Cephalexin Monohydrate	IBI.
61–923	Amoxicillin Trihydrate	Do.
62–052	Nystatin Ointment, U.S.P.	Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.
62–430	Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, U.S.P.	Pharmafair, Inc., 110 Kennedy Dr., Hauppauge, NY 11788.
62–449	Cephalothin Sodium	IBI.
62–666	Cephalothin Sodium for Injection, U.S.P., 1 gram (g) and 2 g	Fujisawa USA, Inc., Parkway North Center, Three Parkway North, Deerfield, IL 60015–2548
62–710	Cephalothin Sodium	IBI.
62–747	Clindamycin Phosphate Injection, U.S.P., 150 mg/milliliters (mL)	Fujusawa USA, Inc.

ANDA No.	Drug	Applicant
80–041	Trisulfapyrimidines Oral Suspension, U.S.P., 0.5 g/5 mL	Solvay Pharmaceuticals, Inc.
80–921	Vitamin A Capsules, U.S.P., 50,000 units	Lemmon Co.
83–993	Phendimetrazine Tartrate Tablets, U.S.P., 35 mg	Solvay Pharmaceuticals, Inc.
84–435	Meprobamate Tablets, U.S.P., 200 mg	Do.
85–897	Phendimetrazine Tartrate Capsules, U.S.P., 35 mg	Do.
87–074	Diatrizoate Meglumine and Diatriozoate Sodium Injectin, U.S.P.	Mallinckrodt Medical, Inc., P.O. Box 5840, St. Louis, MO 63134.
87–113	Triamcinolone Acetonide Cream, U.S.P. 0.1%	Solvay Pharmaceuticals, Inc.
87–210	Reserpine, Hydralazine Hydrochloride, and Hydrochlorothiazide Tablets, U.S.P., 0.1 mg/25 mg/15 mg	Do.
87–833	Prednisone Tablets, U.S.P., 25 mg	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216–6532
88–071	Dexamethasone Sodium Phosphate Ophthalmic Ointment, U.S.P., 0.05%	Pharmafair, Inc.
88–612	Phentermine Hydrochloride Capsules, U.S.P., 30 mg	Lemmon Co.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective March 31, 1995.

Dated: February 16, 1995.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 95–5060 Filed 2–28–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0050]

Drug Export; Sandostatin (Octreotide Acetate) Lar® Injection; 10-Milligram (mg), 20-mg, and 30-mg Vials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sandoz Pharmaceuticals Corp. has filed an application requesting conditional approval for the export of the human drug Sandostatin (octreotide acetate) LAR® Injection 10-mg, 20-mg, and 30-mg vials to Switzerland for further packaging and marketing.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Sandoz Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936–1080, has filed an application requesting approval for the export of the human drug Sandostatin (octreotide acetate) LAR® Injection 10-mg, 20-mg, and 30-mg vials to Switzerland. This product is a new formulation of octreotide acetate manufactured by a different process which is indicated for aromegaly, malignant carcinoid syndrome, and vipoma. The firm does have approval for Sandostatin Injection. The